



## Part 11 System Compliance Assessment Checklist

**ARTICLE EXCERPT BEGINS**

Validation & System Documentation				
#	Rule Section	Requirement	Requirement Satisfied?	Compliance Action
1.	11.10(a) Validation of systems...	<p><b>The system is validated.</b></p> <p><u>Examples</u> of materials in a system validation package include:</p> <ul style="list-style-type: none"> <li>• System Documentation               <ul style="list-style-type: none"> <li>- Approved Requirements</li> <li>- Design Documentation</li> <li>- System Inventory Documentation (HW &amp; SW)</li> </ul> </li> <li>• System Testing               <ul style="list-style-type: none"> <li>- Risk Assessment / Classification</li> <li>- Test Plan</li> <li>- Test Report</li> </ul> </li> <li>• System Maintenance Information               <ul style="list-style-type: none"> <li>- Training Records</li> <li>- Backup Procedures / Disaster Recover Plan</li> <li>- Change Management (Version Control) Procedures</li> <li>- Application Support Documentation</li> </ul> </li> </ul>	<p><b>YES</b></p> <p>Options: YES, NO or n/a</p>	<p><b>MSVM</b></p> <p>Identify the methodology to be used for validation.</p> <p>approved system validation methodology.</p> <p>For existing systems, please contact the Business Unit Part 11 Compliance</p> <p>Owner to help assess validation status.</p>
2.	11.10(k) -1 Adequate controls over...documentation...	Controls are present for the distribution, access and use of systems documentation for operation and maintenance.	<p><b>YES</b></p> <p>Options: YES, NO or n/a</p>	
3.	11.10(k) -2 Revision and change	Systems documentation reflects development and modifications of the system	<p><b>YES</b></p> <p>Options:</p>	

Training & SOP			
4.	11.10(i) Persons who develop, ...have the education, training, and experience...	There is evidence of qualification (education, training or experience) for persons who <b>developed</b> the system.  <b>Note: The appropriate level of Part 11 training should also be provided.</b>	<b>YES</b>  Options: YES, NO or n/a
5.	11.10(i) Persons who maintain, ...have the education, training, and experience	There is evidence of qualifications (education, training or experience) for persons who <b>maintain</b> the system.  <b>Note: The appropriate level of Part 11 training should also be provided.</b>	<b>YES</b>  Options: YES, NO or n/a
6.	11.10(i) Persons who... use...have the education, training, and experience...	There is evidence of qualifications (education, training or experience) for persons who <b>use</b> the system.  <b>Note: It may be appropriate for some key users to also receive Part 11 training.</b>	<b>YES</b>  Options: YES, NO or n/a
7.	11.10(j) Written policies...for actions initiated under...electronic signatures	If electronic signatures are used, a policy is actively implemented, so that individuals understand the significance of, and are held accountable for, their electronic signatures.  <b>Note: This requirement is met by the Business Unit implementing Corporate Part 11 policy _____ that addresses the significance of electronic signatures.</b>	<b>YES</b>  Options: YES, NO or n/a

Record Integrity & Protection			
8.	11.10(a) Ability to discern invalid or altered records	There is a method to <b>detect</b> changes made to records (including direct record changes that bypass system controls).	<b>YES</b>  Options: YES, NO or n/a
9.	11.10.(c) Protection of records...	There is a method to <b>protect</b> records from accidental or deliberate damage (including direct record changes that bypass system controls).	<b>YES</b>  Options: YES, NO or n/a

Record Output			
10	11.10(b) Generate accurate and complete copies...in both human readable...	The system has the ability to produce complete copies of records in <b><u>printed human readable format</u></b>	<b>YES</b> Options: YES, NO or n/a
11	11.10(b) Generate...in... electronic form...	The system has the ability to produce complete copies of records in a <b><u>common electronic format</u></b> (e.g., ASCII, TXT, DOC, XLS, etc.).	<b>YES</b> Options: YES, NO or n/a
Sequence & Device Control			
12	11.10(f) Enforce permitted sequencing of steps and events...	The system controls the required sequencing of steps and events, <u>as appropriate</u> .	<b>N/A</b> Options: YES, NO or n/a <b>Note: Mark as N/A unless identified as a requirement of the system</b>
13	11.10(h) Use of device checks...	The system checks that data entries or operating instructions originate only from authorized locations (e.g., work-stations), <u>as appropriate</u> .	<b>YES</b> Options: YES, NO or n/a <b>Note: Mark as N/A unless identified as a requirement of the system</b>
Application Security & User Authority			
14	11.10(d) Limiting system access	System access is limited to only authorized individuals.	<b>YES</b> Options: YES, NO or n/a

**END OF ARTICLE EXCERPT**



This article excerpt is compliments of the FDA Compliance Learning Community of enKap (<http://www.enkap.com>).

This document will be published in its entirety in the January 2010 Premier Issue of the *FDA Compliance Digest*.